

REGULATION AND PREQUALIFICATION DEPARTMENT

VACCINES ASSESSMENT TEAM

TEMPLATE

Standard Letter A - Notification of Specification Withdrawal

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Standard letter A - Notification of specification withdrawal

Dear Sir/Madam,

Proposed withdrawal of IMD-PQS performance specification

We refer to the WHO IMD-PQS performance specification <reference, title and date>. We write to advise you that it has been decided that this specification no longer meets the needs of the immunization programme. The principal reasons for this are as follows:

< reasons> (Example:)

Project Optimize reported that battery system failure accounted for the majority of first generation solar-powered vaccine appliance equipment failures. In response IMD-PQS established a category for battery free solar direct drive appliances.

IMD-PQS RF06 relies on a battery to sustain acceptable vaccine storage temperatures. Technology has advanced since the initial publication of RF06 and demonstrates that an ancillary battery is not necessary for solar direct drive operation. Of the <insert number> solar direct drive appliances presently prequalified <insert number> are battery free and comply with the RF05 category with no ancillary battery.

The RF06 specification was revised and published on 15 September 2016. The revision informed the discontinuation plan for the specification stating: 'The RF06 category will expire and no longer be prequalified after two years from the date of this revision.'

PQS E003 RF05.4 Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive without battery storage remains in effect and allows the prequalification of solar direct drive appliances.

Your company currently has prequalified product(s) conforming to this specification listed on the IMD-PQS database. As a matter of courtesy, we write to inform you that we intend to withdraw this specification in six months` time on <dd.mm.yy>4.

Yours faithfully,